EXHIBIT "D"

MDMA: Compound raises medical, legal issues

BRAIN MIND bulletin
FRONTIERS OF RESEARCH, THEORY AND PRACTICE
April 15, 1985
Volume 10, Number 8

MDMA, a compound sometimes known as Adam or XTC, is in the eye of a paradoxical hurricane. It appears likely to become tightly restricted just as it is gaining attention as a possible pharmacological breakthrough.

The drug — technically 3,4-methylenedioxy-methamphetamine — is derived from oil of sassafras or oil of nutmeg. Increasingly, psychiatrists and counselors are praising its therapeutic efficacy. Clinical use is being investigated independently by therapists in the U.S., England, Chile, Germany, France and Australia.

Meanwhile the U.S. Drug Enforcement Administration has begun hearings on its possible scheduling as a controlled substance. It also is under international regulatory consideration by the World Health Organization.

DEA officials expressed astonishment at the number of protests from mental-health professionals when the proposed scheduling was announced. Research proponents of the drug requested a hearing through Dewey, Ballantine, Bushby, Palmer & Wood, a prestigious Washington, D.C., law firm.

"We were not aware of the quasi-therapeutic use of the drug until after we proposed scheduling last July," DEA spokesman Frank Sapienza told B/MB. (July 84)

Sapienza said the agency had known of the drug since the 1970's but had not seen reports of its experimental use until recently.

MDMA was one of eight compounds investigated in Michigan animal studies in 1953-54, funded by the Army Chemical Center. The studies were declassified in 1969 and reported in a technical journal in 1973.

The spread of MDMA use and its possible outlawing have provoked a journalistic flurry. *Newsweek, Psychology Today, People, Rolling Stone, California Magazine, L.A. Weekly* and *Omni* are among the publications that have scheduled articles on MDMA.

Separate stories in this issue deal with MDMA's unique characteristics, its purported therapeutic potential and the issues surrounding its current legal status.

Because MDMA's 1914 patent by Merck & Co. has long since lapsed and the compound is now in the public domain, pharmaceutical manufacturers are not motivated to spend the millions of dollars necessary to demonstrate efficacy or safety. In that sense it is what has been called an "orphan drug."

Used legally by psychiatrists in some states and unofficially by non-MD therapists, MDMA has been described by some researchers as an aid to communication and clarity.

Reported therapeutic benefits include insight into problems, pain reduction, motivation, improved couple and family relationships, enhanced body awareness, diminution of fear and treatment of addiction.

The effects of a 100-mg. dose of MDMA last for about four hours. Therapeutically the drug is not taken regularly like a tranquilizer but is used episodically in two or three sessions. The drug does not lend itself to abuse because the brain

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Psychiatrists report on drug's clinical outcome

Four psychiatrists who use MDMA in clinical practice reported on the findings of more than 1,000 sessions at a recent California conference sponsored by the Earth Metabolic Design Laboratory.

Their overall conclusions, as phrased in an article in press: "The reports of MDMA's facilitation of psychotherapy were impressive. Many subjects experienced classic retrieval of lost traumatic memories, followed by relief of emotional symptoms."

Psychotherapist Alise Agar will coordinate a follow-up meeting of psychiatrists, psychologists, chemists and others in June to synthesize the findings to date.

MDMA currently is used for cancer patients as an adjunct to conventional therapy. Patients say the experience alters their sense of hopelessness. Some have significantly outlived their prognoses. One reported becoming pain-free during the session after a year of intense pain. With the help of self-hypnosis and two more MDMA sessions, he has been able to maintain the pain at a low level for six months.

Psychiatrist George Greer concluded that his study of 29 patients demonstrated "a potential use for MDMA as a safe and effective adjunct to therapy, especially for the prevention and treatment of interpersonal problems and substance-use

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Hearing to determine MDMA research status

Witnesses on both sides of the MDMA issue are squaring off.

In the upcoming MDMA hearings, UCLA psychologist Ron Siegel will testify on abuse by recreational users he has interviewed. Government witnesses will testify that its use as a treatment adjunct has not been established. They also will cite animal tests showing "similar qualitative effects" between MDMA and MDA.

MDMA researchers — psychiatrists George Greer of Santa Fe, N.M., and Lester Grinspoon of Harvard Medical School, law professor James Bakalar of Harvard, educational psychologist Thomas Roberts of Northern Illinois University — maintain that MDMA does not have a high potential for abuse. "At most it has a low or moderate potential." That position also will be taken by psychiatrist Lance Wright of the drug and alcohol treatment unit of the Philadelphia VA Medical Center and physician Richard Seymour of the Haight-Ashbury Free Medical Clinic.

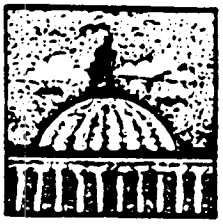
The investigators also will argue that, judging by current use of MDMA by practicing psychiatrists, the compound is safe under medical supervision and has shown significant therapeutic value.

According to Grinspoon, the government has performed no controlled studies on the substance. In late March the National Institute on Drug Abuse allocated $25,000 to determine dependency potential in rats and monkeys.

The research proponents will cite a new study on rats that appears to contradict the earlier finding of similarity to MDA. First, scientists trained the animals to differentiate between LSD and a saline solution. When the animals were then given MDA, they behaved as if they had been given LSD. MDMA produced a diff[illegible]

DEA, clinicians disagree on MDMA scheduling

The legal controversy surrounding MDMA raises provocative questions: Who should control the use of new therapeutic agents? Who should define "potential for abuse" or "accepted medical use"?



According to U.S. law, foods and drugs are regulated for safety by the Food and Drug Administration. The Drug Enforcement Administration, as part of the Justice Department, is responsible for enforcing laws.

A qualified researcher or pharmaceutical company files a request to investigate a new drug. Animal studies explore chronic toxicity, determining which organs are damaged after prolonged use. After animal toxicity levels are established, researchers can investigate safety and efficacy in human subjects.

The typical procedure to get a new drug approved costs the pharmaceutical manufacturer some $12 million. Because MDMA was first patented in 1914 and is now in the public domain, there is little incentive for a manufacturer to seek its approval.

(When lithium, a natural element, was found to be effective in the treatment of manic-depressive illness, psychiatrists were frustrated because manufacturers had no financial motivation to process it and verify its purity. As a known compound, it could not be patented. However, a special spansule form was finally patented to get around the problem.)

Canada is the only country in which MDMA is illegal. The substance was scheduled there in 1979 after unofficial manufacture came to light.

Since it is not yet scheduled in the U.S., MDMA is in a legal twilight zone. It can be used on human subjects in states where physicians are allowed to administer drugs they have manufactured to consenting patients. State laws require them, however, to gain informed consent and peer review of their work.

All other investigations are necessarily off the record and cannot be officially considered by the DEA. Therefore there is no body of data on safety and medical efficacy for most new substances.

Drugs with no official standing are subject to being "scheduled"—that is, made illegal except for use by registered researchers—if a potential for abuse is uncovered. A drug is proposed for Schedule 1 if it is considered to have high abuse potential and no medical efficacy. Schedule 2 if it has high abuse potential and acknowledged medical utility. LSD is Schedule 1; morphine, cocaine and amphetamine are Schedule 2.

Schedules 3, 4 and 5 cover drugs of decreasing abuse potential and broader—almost lay—medical use. They do not even require triplicate prescriptions.

The DEA points out that qualified researchers technically can study Schedule 1 drugs. However, research proponents say that the stringent Schedule 1 protocols discourage study. They point out that no drug has ever been removed from Schedule 1.

Only one researcher in the U.S., Franco DiLeo of the University of Maryland Medical School, has obtained permission to investigate LSD. DiLeo is studying its use in the terminally ill.

Therapists see MDMA as useful. . .

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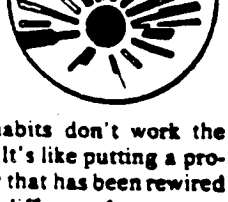
disorders."

The most common benefits: improved communication and intimacy between family members and couples. Aftereffects included higher self-esteem, positive mood and a decreased use of addictive substances.

Most subjects reported an expanded mental perspective or insight. Several said they felt undesirable emotional symptoms, such as anxiety during the sessions and sadness or fatigue afterward. Five described transcendent experiences.



All nine with specific psychiatric disorders reported significant relief from their problems. Two said they had full and lasting remissions.

"When we are in altered states, our habits don't work the same," Greer said. "It's like putting a program into a computer that has been rewired or is operating at a different frequency.

"The usual pattern of flow keeps running into dead ends. The computer keeps asking the operator what to do, so the operator has to make a choice.

"The brain works similarly. Because the drug alters the brain chemistry, it changes the way nerve cells communicate with each other. Because habitual patterns don't work, our brains ask us which way to go a lot more often.

"To the extent that our purpose is easily realized, this can be a wonderful experience. But if we do not know what our purpose is, the experience can be difficult. The difficulty pushes us either to change our purpose or to change ourselves in order to move nearer our chosen goal.

"Through this experience, one can decide to learn simpler, more efficient ways of being able to recognize and make choices—without having to spend a lot of time in a drug-induced state."

David Katzin, a Los Angeles physician who directs a drug detoxification clinic, suggested that MDMA may prove useful for substance abuse. Another physician has already used it successfully to assist cocaine withdrawal.

A Benedictine monk working in a state prison has suggested using MDMA in the rehabilitation of prisoners. An unofficial study of psychiatric residents at Harvard University will examine the usefulness of the compound as a training tool for clinicians, and a West Coast psychiatrist recently proposed a study of MDMA as a motivational tool for vocational rehabilitation.

In Brief

Psycho-Imitative Training May 4-5; advanced version May 6-8, "demystification of the psychic process," with Anne and Jim Armstrong, Paradise Valley, Ariz., (602) 941-7121. . . . **Council of Schools and Spirit of Nature** May 11-26, ongoing meeting with Rupert Sheldrake, Joan Halifax, Ralph Abraham, John and Toni Lilly, Lynn Andrews, others; Ojai, Calif., (805) 646-8343. . . . **Neuro-Linguistic Programming** May 11-12, introductory seminar, San Francisco, (415) 927-0511 . . . . **Optimalearning/Suggestology** May 17-19, San Francisco, (415) 383-1717. . . . **Theory and Practice of Gestalt Therapy** May 17-19, Cape Cod, Mass., (914) 691-7192. . . . **Taking the Quantum Leap** May 17-19; **Star Wave: Mind, Consciousness and Quantum Physics** May 19-23, workshops with Fred Wolf on new physics, Reno, (702) 323-0378.

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BOOKS

Psychology moves from upset mind to broken brain

THE BROKEN BRAIN by Nancy Andreasen ($16.95 from Harper & Row, 10 East 53rd St., NYC 10022).

Drugs are reshaping the direction of psychiatry. "Designer drugs," made precisely to fit the brain's receptors, can alter moods in exact ways, providing relief from alarming disorders. They may one day be used to heighten specific kinds of awareness or enhance specific skills.

This highly accessible book on the biological revolution in psychiatry is a good introduction. But it is clearly biased: Andreasen, a psychiatry professor, believes that most mental illness is *caused* by abnormalities in brain structure or chemistry. As psychiatry moves from a psychological to a neuroscience explanation, she says, it is moving from the "troubled mind" to the "broken brain."

Andreasen aims to remove the stigma from mental illness—and to remove the stigma from using drugs to treat it.

After reviewing the two other schools of thought on mental disorders — psychoanalysis and behaviorism — she introduces the biological model: Psychiatric illnesses are medical diseases just like diabetes, heart disease and cancer. They are not due to "bad habits," bad parenting or weakness of will, she asserts. Therefore, they should be treated by "somatic therapies."

Andreasen contrasts these three approaches, introducing beginners to the brain and its array of neurotransmitters, and reviewing the history of new pharmacological treatments.

In her enthusiasm for these breakthroughs, however, she may be oversimplifying this issue. Depression, schizophrenia and anxiety cannot be explained away on purely materialistic bases. Given the great body of evidence for the role of stress and attitude in physical illnesses, it is unreasonable to seek a single biological cause for mental illness.

Andreasen does not differentiate between *cause* and *symptom*. She assumes, rather, that the cause is always in the physical brain.

Revolutionary new drugs may alter brain function in a way that enables people to work, focus and generally feel better. But do they "cure" people? What is the therapeutic competence in the world of mental disease? And do biological psychiatrists continue to seek answers to these questions while easing life for their patients? —C.Z.

Tomatoes, tradition and curiosity

The reason tomatoes were not accepted until relatively recently in North America is simple: They were poisonous. Everyone knew they were poisonous, at least everyone in North America. It was obvious.

Tomatoes belong to the nightshade family. . . . The fact that the French and Italians were eating them in increasing quantities without seeming harm did not encourage colonial Americans to try them. It simply did not make sense to eat poisonous food.

Not until 1820, when Robert Gibbon Johnson ate a tomato on the steps of the courthouse in Salem, N.J., and survived, did the people of America begin, grudgingly, we suspect, to consume tomatoes.

The tomato effect in medicine occurs when an efficacious treatment for a certain disease is ignored or rejected because it does not 'make sense' in light of accepted theories of disease mechanism and drug action. The tomato was ignored because it was clearly poisonous; it would have been foolish to eat one. In analogous fashion, there have been many therapies in the history of medicine that, while later proved efficacious, were at one time rejected because they did not make sense. . . .

We cannot progress in medicine without a theoretical structure. Structure by necessity limits our peripheral vision while allowing us to focus on a particular path. The benefit of such a structure far outweighs the detriment. However, we can reduce the detriment by asking, almost in ritual fashion, certain questions. Before we accept a treatment, we should ask, "Is this a placebo?"; before we reject a treatment we should ask, "Is this a tomato?"

—*Journal of the American Medical Assn.*, May 11; reprinted in *Advances* 2:1

WHO to rule on 28 phenethylamines

International attempts to regulate MDMA and a family of related compounds are under way.

In the late 60's and early 70's, 40 nations signed treaties to coordinate drug controls worldwide. With the International Convention of Psychotropic Substances, scheduling procedures became uniform.

Rulings by the World Health Organization take precedence over national ones. A country can favor higher national recommendations but not lower ones.

Late this month in Geneva the Expert Committee on Drug Dependence will convene to recommend various levels of control over MDMA and 27 other phenethylamines. Next February member nations will meet for official voting.

In 1958 a WHO technical report o psychoactive drugs in psychiatry explore the relationship between altered states an religious experiences and noted the relu tance of scientists to enter into full-sca investigation of these areas.

Last May WHO passed a resolutio urging the recognition of "the spiritu dimension of health." Richard Doblin, spokesman for the Earth Metabolic Desi foundation, suggests that the resolution a context in which WHO could update t 1958 report by reviewing the medical pects of the new compounds.

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FRONTIERS OF RESEARCH, THEORY AND PRACTICE

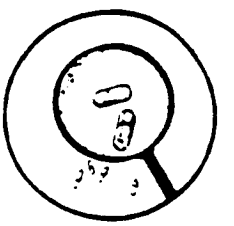
Psychiatrists, drug-abuse specialists testify in L.A. at first MDMA hearing

The first of a round of hearings on MDMA was held in Los Angeles in June just weeks before the substance was made illegal July 1 under a one-year emergency action by the U.S. Drug Enforcement Administration.

Three psychiatrists testified for the research proponents, who are requesting that the DEA place the drug in Schedule III of its regulations rather than the more stringent Schedule I. The petitioners maintain that "Draconian" Schedule I requirements will make research almost impossible.

Another hearing is set for Kansas City July 10, to be followed by a third in Washington, D.C., probably in September.

After the Washington hearing, Francis Young, the federal administrative law judge, will make his recommendations to the DEA. The agency is not bound by the judge's recommendation.



Young has criticized the DEA for "pre-judging" the primary issue in the case, the possible medical utility of MDMA and its potential for abuse.

Because MDMA was patented early in the century and is now in the public domain, there is no financial incentive for pharmaceutical manufacturers to invest in its testing. Also, since it is used episodi-

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Psychiatrists ask DEA Schedule III for MDMA. . .

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cally as an aid to therapeutic insight, it would never be prescribed as an ongoing medication like tranquilizers.

The actual petitioners in the hearings are Lester Grinspoon and James Bakalar of Harvard Medical School, Thomas Roberts of Northern Illinois University and George Greer, a Santa Fe, N.M., psychiatrist. Greer is the only petitioner using MDMA clinically.

Two staff members of the Haight-Ashbury Clinic in San Francisco, one called by each side, offered their views of the drug's abuse potential.

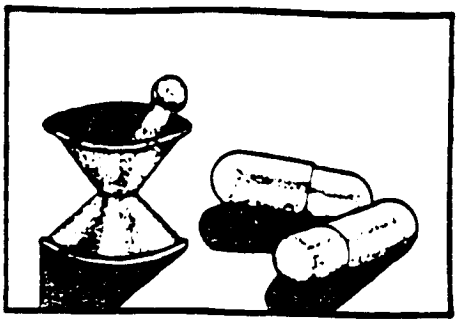
Daryl Inaba, a physician on the Haight-Ashbury staff, a government witness, said that about one per cent of the clinic's clients report abuse of drugs in the MDA-MDMA family. Under cross-examination by Richard Cotton, attorney for the research proponents, Inaya acknowledged that drug users are frequently wrong in their identification of the substances they abuse.

Inaba testified that the number of cases of MDMA abuse had not changed appreciably over the past decade. He himself saw "one or two clients per year in that category."

Rick Seymour, director of education and training at the clinic, a witness for the research proponents, testified that he had seen little abuse of MDMA.

Psychiatrists Jack Downing and Phil Wolfson talked about their use of MDMA to facilitate communication and insight.

Robert Lynch, statewide psychiatric consultant to the California Department of Rehabilitation, told of his own MDMA experience in an experimental setting. Lynch filed an investigational new drug



application with the Food and Drug Administration. He hopes to explore the motivational uses in rehabilitation.

A DEA official told *B/MB*: "If the reports are true, this may be a facilitator rather than a treatment—something that helps individuals open up with the therapist."

The unusual nature of the drug—its role as an enhancer of learning, insight and communication—may be the catch. The U.S. Pharmacopoeia has no category for drugs that are not specific treatments.

The DEA maintains that Schedule I drugs can, in fact, be used in research. Marijuana, a Schedule I drug, has been used to relieve the pressure of glaucoma and the nausea associated with chemotherapy.

Frank Sapienza, a senior DEA official, said in an interview that the "hitch" in Schedule I is the requirement for protocol approval by the FDA. Pharmaceutical companies typically spend around $10 million bringing a drug from animal testing through approved status for prescription for human use.

Two major pharmaceutical companies have joined the action, not because they are interested in MDMA but in protest of what they consider the DEA's arbitrary placement of substances in Schedule I, which makes approval unusually difficult.

Asked how the research protocols for Schedule III would differ from Schedule I, Sapienza said that the DEA has, in fact, no protocols designed for Schedule III.

The research proponents have pointed out that the DEA also has no advisory panel experienced in the use of psychoactive drugs like MDMA. They have offered to help establish a committee of experienced researchers to evaluate protocols.

Since *Brain/Mind Bulletin's* special issue on the medical and legal issues surrounding MDMA controversy (April 15), the drug has become a cause celebre. A *Newsweek* story led to news coverage by the three major television networks, the Phil Donahue show and widespread newspaper and magazine attention, including a cover story in *New York* magazine, a forthcoming *Life* article and a British TV special.

In its list of 28 phenethylamines proposed for scheduling, the World Health Organization has now added a paragraph noting that there is anecdotal evidence that MDMA may have therapeutic value. It encourages research by member nations.

Background information on MDMA: Earth Metabolic Design Foundation, (415) 420-9739. Regulatory information from the Drug Enforcement Administration, Department of Justice, Washington 20537.

Key points of MDMA testimony

Key points of the psychiatrists' testimony:

• MDMA is a unique agent in their experience. Robert Lynch called it an "empathogen." Phil Wolfson called it a "psychic integrator."

Wolfson proposed that MDMA be designated a new kind of compound. "It has aspects of a tranquilizer, a stimulant, an anti-anxiety agent, an anti-psychotic and an anti-depressant. It contains seeds from many different realms. However, in and of itself, it is a different experience than any available with known medicines."

• Lynch testified that improvement persists; the experience "sticks to your ribs."

• Jack Downing said that "overall, mental capability was accentuated." There is no "Wheee!" feeling as in alcohol, marijuana or the sedatives. He and Lynch said that MDMA apparently does not inhibit the cortex from its usual control. He described a psychophysiological study of 21 individuals showing no significant toxicity. He also reported that five of eight therapy cases improved significantly.

• Wolfson described his use of MDMA in family therapy and psychiatric disorders, including psychosis. He said the substance has a short-term but powerful anti-manic effect.

"MDMA tends to have an anti-paranoid effect and to open discourse between people. . . . As an experience, it lingers long beyond the activity of the drug itself. That is to say, MDMA is a learnable experience. One can develop the ability to return to its peaceful landscape without the drug."

The ability to learn the state without the drug may account for the low abuse potential of MDMA, he said.

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Government witness says MDMA deserves study

During four days of hearings in Washington last month, a government witness surprised observers by offering the strongest testimony in favor of further research on MDMA.

John Docherty, former chief of the Psychosocial Treatment Research branch in the National Institute of Mental Health, told the court that only one variable has been shown to be reliably significant in psychiatry—the rapport between patient and therapist. MDMA, he said, is unique in its reputed potential for enhancing that rapport.

Docherty, now medical director of Nashua (N.H.) Brookside Hospital, said MDMA is at the confluence of the two great trends of psychiatry: psychotherapy and pharmacology.

Brain Mind BULLETIN
NEWS FROM THE LEADING EDGE
November 18, 1985
Volume 11, Number 1

Although the drug became the focus of national media attention last spring, no representatives of the press attended the public hearings, which will bear on the official government status of MDMA.

The Drug Enforcement Administration, a branch of the Food and Drug Administration, is requesting the most restrictive category, Schedule I. A number of researchers are requesting a Schedule III rating, which they maintain would make it easier to investigate a tool of unusual psychotherapeutic potential.

In support of the government's contention that placement in Schedule I does not discourage research, witnesses for the Food and Drug Administration said that two dozen or so projects involving Schedule I drugs had been approved. Under cross-questioning, the FDA witness acknowledged that all but one project involved the

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MDMA hearing. . .

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study of marijuana for its well-established use in glaucoma and the nausea caused by chemotherapy.

The director of clinical research for the Hoffmann-LaRoche pharmaceutical company testified that his firm would not undertake the study of a Schedule I drug unless it had the potential for saving lives. Otherwise, he said, it was not worth the red tape.

He added that most pharmaceutical research is farmed out to university researchers. If told that Schedule I drugs are officially "of no known medical utility" and "highly subject to abuse," he said, neither researchers nor volunteers would take part.

Hoffmann-LaRoche and a pharmaceutical subsidiary of Johnson & Johnson had joined the case, contending that the Schedule I classification makes investigation of a new drug unfeasible.

Meanwhile, a new rider on a Senate "designer drug" bill would make it a misdemeanor to possess any drug similar in structure or effect to a Schedule I or II substance unless it was used in an FDA-approved new-drug investigation (IND).

Psychiatrists supporting the investigation of MDMA plan to seek an amendment exempting those researchers with formal protocols. The bill could then sanction approved MDMA studies.

Attorneys for both sides will file briefs and counter-arguments over the next several months. After taking the case under advisement, the judge will make his recommendation. The DEA is not bound by his determination.